American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

September 17, 2002

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852
http://www.fda.gov/dockets/ecomments

Docket Number: 01P-0120

Dear Sir or Madam:

The American Academy of Pediatrics (AAP) welcomes the opportunity to provide information to the Food and Drug Administration on needlestick prevention technology as requested in the June 20, 2002 ***Federal Register*** Notice (Volume 67, Number 119). We commend the FDA for soliciting this input to ensure that the quality of patient care is not compromised by premature efforts to ban specific products, impose performance standards, and labeling requirements on sharps devices. On behalf of our 57,000 pediatricians, pediatric medical and surgical specialists, pediatric dentists, and our patients, the Academy is responding to your specific requests. **However, our fundamental concern remains: The special problems around veinous access for small infants have been complicated by engineering challenges around "safe sharps". We recommend that efforts be focused on these situations and on the impact of current guidelines and product changes around immunizations, one the most difficult and one of the most common procedures putting clinicians and children at risk from sharps injuries.**

Banning Sharps Devices
The FDA requested information and insights on the basis for banning one or more of these devices and the impact of such bans on patient care and healthcare worker safety (*III HRG/SEIU Petition, A. Banning- page 41892).*

- For infants and very young children the technical issues are vessel fragility and caliber. In general, the current needleless devices that are smaller than 18G are not efficacious for this patient group. Multiple puncture attempts are often necessary to achieve access even with skilled individuals. Not unexpectedly, the situation is variable in different clinical settings.

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- The adverse results of multiple punctures include
    1. Increased pain for the infant/child
    2. Increased nosocomial infection risk
    3. Psychogenic trauma to child and family
    4. Delay in initiation of specific therapy
    5. Increased trauma to a limited number of access vessels resulting in the requirement for more invasive procedures for IV access both for routine and for emergent care. This latter is particularly true for hospitalized infants and children requiring prolonged IV therapy or parenteral nutrition.

- Manufacturers must show that their device(s) perform adequately in the clinical settings where infants and children require IV access before being released to the market. i.e., successful achievement of IV access with a single attempt with diverse personnel in the full spectrum of pediatric ages a specified percentage of the time. (75%). Or successful achievement of IV access at a similar rate after training as previous devices.

- Detailed injury information on specific sharps devices (manufacturer, product, did injury occur following manufacturer instructions for use, etc) does not exist. Therefore it would be premature to ban products based on the 1992 criteria for safety alone. Premature banning adversely affects quality of care if products are banned for which safer alternatives are not yet available on the market.

- Better to allow the market forces to work. As hospitals and health care facilities inquire annually about the availability of safer products (per the ECP) this will create demand to which manufacturers will respond.

- Unique patient populations (premature infants, special needs pediatric patients) are often slow to get new well-designed, effective products, as the market is so small. Even when products become available they are not always effective for infants and neonates.

Application of the Performance Standard Criteria

The FDA requested information addressing the appropriateness of developing a performance standard based on these or other criteria. The FDA also invited discussion on voluntary consensus standards (*III HRG/SEIU Petition, B. Performance Standard - page 41892).*

- Engineering controls do not prevent all Percutaneous Sharps Injuries. According to the CDC 6% injuries occur before use, 20% during use. Very few engineering controls can prevent injuries during these phases.

- Optimal protection of health care workers from blood-borne pathogen transmissions associated with Percutaneous Sharps Injuries, depends on an overall safety plan that includes exposure control plans, work practices, injury reporting and analysis, employee training retraining, enforcement in addition to engineering controls. The current OSHA

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Part # 154254-354 RIT 03/01